Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

VA/DoD clinical practice guideline for rehabilitation of individuals with lower limb amputation.

Bibliographic Source(s)

Rehabilitation of Individuals with Lower Limb Amputation Work Group. VA/DoD clinical practice guideline for rehabilitation of individuals with lower limb amputation. Version 2.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 123 p. [133 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for rehabilitation of lower amputation. Washington (DC): Department of Veterans Affairs, Department of Defense; 2007. 163 p. [71 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition

YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	**Specific and Unambiguous Articulation of Recommendations**
▮▮▮▮▮	**External Review**
▮▮▮▮▮	**Updating**

Recommendations

Major Recommendations

Note from the Department of Veterans Affairs and the Department of Defense (VA/DoD) and the National Guideline Clearinghouse (NGC): The recommendations for the management of posttraumatic stress disorder are organized into 4 sections (A-D below) and 2 modules with 2 algorithms. The accompanying recommendations are provided below. See the original guideline document for the algorithms and evidence tables associated with selected recommendations, including level and quality of evidence, strength of recommendation, and supporting evidence citations.

The strength of recommendation grading (Strong For, Weak For, Strong Against, Weak Against) and recommendation categories (Reviewed, Not reviewed, New-added, New-replaced, Not changed, Amended, Deleted) are defined at the end of the "Major Recommendations" field.

A. All Phases of Amputation Rehabilitation

The Work Group suggests that patient education be provided by the rehabilitation care team throughout all phases of amputation rehabilitation. (Weak For; Reviewed, Amended)
The Work Group suggests an assessment of behavioral health and psychosocial functioning at every phase of amputation management and rehabilitation. (Weak For; Reviewed, Amended)
When assessing pain, the Work Group suggests that measurement of the intensity of pain and

interference with function should be separately assessed for each pain type and location using standardized tools. (Weak For; Reviewed, Amended)

The Work Group suggests offering a multi-modal, transdisciplinary individualized approach to pain management including transition to a non-narcotic pharmacological regimen combined with physical, psychological, and mechanical modalities throughout the rehabilitation process (For the treatment of chronic pain, the NGC summary of the 2017 VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain recommends alternatives to opioid therapy such as self-management strategies, other non-pharmacological treatments, and non-opioids over opioids. (Weak For; Reviewed, New-replaced)

The Work Group recommends providers consider the patient's birth sex and self-identified gender identity in developing individualized treatment plans. (Strong For; Reviewed, New-added)

The Work Group suggests offering peer support interventions, including visitation by a certified peer visitor, as early as feasible and throughout the rehabilitation process. (Weak For; Reviewed, Amended)

B. Perioperative Phase

Prior to surgery, the Work Group suggests that rehabilitation goals, outcomes, and other implications be included in shared decision making about residual limb length and amputation level. (Weak For; Reviewed, Amended)

There is insufficient evidence to recommend one surgical amputation procedure over another. (Not Applicable; Reviewed, New-added)

The Work Group suggests the use of a rigid or semi-rigid dressing to promote healing and early prosthetic use as soon as feasible post-amputation in transtibial amputation. Rigid post-operative dressings are preferred in situations where limb protection is a priority. (Weak For; Reviewed, Amended)

The Work Group suggests performing cognitive screening prior to establishing rehabilitation goals, to assess the patient's ability and suitability for appropriate prosthetic technology. (Weak For; Reviewed, New-replaced)

The Work Group suggests that in the perioperative phase following amputation, patients receive physical rehabilitation and appropriate durable medical equipment/assistive technology. (Weak For; Reviewed, New-replaced)

The Work Group suggests, when applicable, treatment in an acute inpatient rehabilitation program over a skilled nursing facility. (Weak For; Reviewed, New-replaced)

The Work Group suggests the initiation of mobility training as soon as feasible post-amputation. In appropriate patients, this may include ipsilateral side weight-bearing ambulation with a pylon to improve physical function and gait parameters. (Weak For; Reviewed, New-replaced)

The Work Group recommends instituting rehabilitation training interventions, using both open and closed chain exercises and progressive resistance to improve gait, mobility, strength, cardiovascular fitness and activities of daily living performance in order to maximize function. (Strong For; Reviewed, New-replaced)

C. Pre-Prosthetic Phase

The Work Group suggests offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces. (Weak For; Reviewed, New-added)

D. Prosthetic Training Phase

The Work Group recommends the use of valid, reliable, and responsive functional outcome measures, including, but not limited to, the Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, and 6-minute walk test. (Strong For; Reviewed, New-replaced)

The Work Group suggests the use of a combination of measures with acceptable psychometric properties to assess functional outcomes. (Weak For; Reviewed, New-replaced)

The Work Group recommends an assessment of factors that are associated with poorer outcomes following acquired limb loss, such as smoking, comorbid injuries or illnesses, psychosocial functioning, and pain. (Strong For; Reviewed, Amended)

Definitions

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Using these elements, the grade of each recommendation is presented as part of a continuum:

Strong For (or "The Work Group recommends offering this option …")
Weak For (or "The Work Group suggests offering this option …")
Weak Against (or "The Work Group suggests not offering this option …")
Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

For use in the 2017 lower limb amputation (LLA) clinical practice guideline (CPG), a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2007 LLA CPG.

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

Clinical Algorithm(s)

The following clinical algorithms are provided in the original guideline document:

Module A: Transdisciplinary Amputation Care Team Approach (TACT)
Module B: Primary Care Follow-up and Lifelong Care

Scope

Disease/Condition(s)

Conditions necessitating lower limb amputation, including:

Dysvascular complications from diabetes, arteriosclerosis, smoking, or a combination
Traumatic causes (motor vehicle and industrial accidents; electrical, chemical and thermal burns; injuries associated with power tool or heavy machinery; combat-related injuries)
Other causes of amputation (malignant musculoskeletal tumors, infection, iatrogenic complications of vascular access procedures for other medical problems, and congenital limb development deficiency)

Note: This clinical practice guideline (CPG) does not specifically address the care of individuals with multiple limb loss.

Guideline Category

Evaluation

Management

Rehabilitation

Treatment

Clinical Specialty

Orthopedic Surgery

Physical Medicine and Rehabilitation

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Occupational Therapists

Physical Therapists

Physician Assistants

Physicians

Podiatrists

Psychologists/Non-physician Behavioral Health Clinicians

Social Workers

Guideline Objective(s)

- To provide guidance to assist healthcare providers in perioperative, pre-prosthetic training, and prosthetic training phases of patient care
- To improve the patient's health and well-being by guiding healthcare providers who are assisting patients in rehabilitation after lower limb amputation (LLA) along the management pathways that are supported by evidence
- To help improve the rehabilitative care of individuals with LLA in the Department of Veterans Affairs (VA) and Department of Defense (DoD) systems

Target Population

Adults 18 years or older with lower extremity amputation treated in any Department of Veterans Affairs (VA)/Department of Defense (DoD) clinical setting

Note: This clinical practice guideline (CPG) does not provide recommendations for rehabilitation of children or adolescents with lower limb amputation (LLA).

Interventions and Practices Considered

1. Patient education
2. Behavioral health assessment
3. Psychosocial functioning assessment
4. Pain assessment (intensity and interference with function) using standardized tools
5. Multi-modal, transdisciplinary individualized approach to pain management
6. Consideration of patient's birth sex and self-identified gender
7. Peer support interventions
8. Shared decision making about residual limb length and amputation level
9. Rigid or semi-rigid dressing
10. Early prosthetic use
11. Cognitive screening
12. Physical rehabilitation
13. Durable medical equipment/assistive technology
14. Acute inpatient rehabilitation program
15. Mobility training
16. Rehabilitation training interventions
17. Microprocessor knee units
18. Functional outcome measures (Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, 6-minute walk test)
19. Assessment of factors that are associated with poorer outcomes (smoking, comorbid injuries or illnesses, psychosocial functioning, pain)

Note: There is insufficient evidence to recommend one surgical amputation procedure over another. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces.

Major Outcomes Considered

- Changes in functional status

- Walking ability
- Quality of life
- Patient satisfaction
- Strength
- Pain
- Morbidity
- Safety (falls)
- Complication
- Amputation
- Gangrene
- Ischemia
- Infection of the contralateral limb

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Developing the Scope and Key Questions

The Clinical Practice Guideline (CPG) Champions, along with the Work Group, were tasked with identifying key questions (KQs) to guide the evidence review of the literature on lower limb amputation (LLA). These questions, which were developed in consultation with the Lewin team, addressed clinical topics of the highest priority for the Department of Veterans Affairs (VA) and Department of Defense (DoD) populations. The KQs follow the population, intervention, comparison, outcome, timing and setting (PICOTS) framework for evidence questions, as established by the Agency for Healthcare Research and Quality (AHRQ). Table A-1 in the original guideline document provides a brief overview of the PICOTS typology.

The Champions, Work Group, and evidence review team carried out several iterations of this process, each time narrowing the scope of the CPG and the literature review by prioritizing the topics of interest. Due to resource constraints, all developed KQs were not able to be included in the systematic evidence review. Thus, the Champions and Work Group determined which questions were of highest priority, and those were included in the review. Table A-4 in the original guideline document contains the final set of KQs used to guide the systematic evidence review for this CPG.

Conducting the Systematic Review

Extensive literature searches identified 3,685 citations published from January 2007 through July 2016 potentially addressing the KQs of interest to this evidence review. Of those, 2,058 were excluded upon title review for clearly not meeting inclusion criteria (e.g., not pertinent to the topic, not published in English, published prior to study inclusion publication date, or not a full-length article). Overall, 1,627 abstracts were reviewed with 1,230 of those being excluded for the following reasons: not a systematic review (SR) or clinical study, did not address a KQ of interest to this review, did not enroll a population of interest, or published prior to January 2007. A total of 397 full-length articles were reviewed. Of those,

206 were excluded at a first pass review for the following: not addressing a KQ of interest, not enrolling the population of interest, not meeting inclusion criteria for clinical study or SR, not meeting inclusion criteria for any KQ, or being a duplicate. A total of 191 full-length articles were thought to address one or more KQs and were further reviewed. Of these, 114 were ultimately excluded. Reasons for their exclusion are presented in Figure A-1 in the original guideline document.

Criteria for Study Inclusion/Exclusion

General Criteria

Clinical studies or SRs published on or after January 1, 2007 through July 31, 2016. If multiple SRs addressed a key question, the most recent and/or comprehensive review was selected. SRs were supplemented with clinical studies published subsequent to the SR.
Studies must have been published in English.
Publication must have been a full clinical study or SR; abstracts alone were not included. Similarly, letters, editorials, and other publications that were not full-length clinical studies were not accepted as evidence.
Study must have enrolled at least 20 patients (10 per study group) unless otherwise noted (see Key Question Specific Criteria below).
Study must have reported on an outcome of interest.
Study must have enrolled a patient population in which at least 80% of patients had lower limb (rather than upper limb) amputation and were age 18 years or older. If the percentage was less than 80%, then data must have been reported separately for this patient subgroup.

Key Question Specific Criteria

For KQs 1, 2, and 4, acceptable study designs included SRs and individual randomized controlled trial (RCTs) not evaluated in SRs. If no relevant studies with these designs were found for a given KQ or sub-question, prospective nonrandomized comparative studies were evaluated for inclusion.
For KQ 3, acceptable study designs included SRs or RCTs that statistically compared outcomes for patients with LLA and various risk factors to outcomes in patients without these risk factors. Observational studies were acceptable if they performed multivariate statistical analyses of the effect of co-occurring conditions on patient outcomes; the minimum patient enrollments were 100 for prospective studies and 200 for retrospective studies.
For KQ 5, acceptable study designs included SRs, RCTs, or prospective cohort studies that compare the accuracy of different measures of function levels and their ability to predict prosthetic and rehabilitation outcomes.
For KQ 6, acceptable study designs included SRs, RCTs, or observational comparative studies that compare different rehabilitation strategies and assessed differential treatment effects in various subgroups of patients.
For KQ 7, 8, and 9, acceptable study designs included SRs, RCTs, or any prospective or retrospective comparative study that addressed the question.
For KQ 10, any study that identified issues unique to females or individuals with varying gender identification compared to males were included.

Literature Search Strategy

Bibliographic Database Information

The Cochrane Database of Systematic Reviews (Cochrane Reviews): 2007 to June 13, 2016 (Wiley)
CINAHL: 2007 to July 6, 2016 (Wiley)
EMBASE (Excerpta Medica): 2007 to July 6, 2016 (Elsevier)
Health Technology Assessment Database (HTA): 2007 to June 13, 2016 (Wiley)
MEDLINE/PreMEDLINE: 2007 to July 6, 2016 (Elsevier)
PsycINFO: 2007 to July 6, 2016 (OVIDSP)
PubMed (In-process and Publisher records): 2007 to July 6, 2016 (NLM)

Gray Literature Resources

AHRQ 2007 to July 7, 2016 (AHRQ)

Additional information on the search strategies, including topic-specific search terms and search strategies can be found in Appendix F in the original guideline document.

Number of Source Documents

Overall, 74 studies (in 77 publications) addressed one or more of the key questions (KQs) and were considered as evidence in this review. See Figure A-1 in the original guideline document for a study flow diagram.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence and Definitions*

High quality — Further research is very unlikely to change confidence in the estimate of effect.
Moderate quality — Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low quality — Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very low quality — Any estimate of effect is very uncertain.

*Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., Schünemann, H. J. & the GRADE Working Group. (2008). GRADE; An emerging consensus on rating quality of evidence and strength of recommendations. *BMJ, 336*, 924-926.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Abstracting and Managing Data

For each study included in this review, the reviewers abstracted the following study level details: country, purpose, and quality rating. For previous systematic reviews, they reported the search strategy used, study selection criteria, and overall information about the evidence base, including number of included studies and overall patients enrolled. For all studies, the reviewers abstracted data about characteristics of the included patients and interventions being assessed.

Assessing Individual Studies' Methodological Quality (i.e., Internal Validity or Risk of Bias)

As per the Department of Veterans Affairs (VA)/Department of Defense (DoD) *Guidelines for Guidelines* document, risk-of-bias (or study quality) of individual studies and previous systematic reviews was assessed using the U.S. Preventive Services Task Force (USPSTF) method. Each study was assigned a rating of Good, Fair, or Poor based on sets of criteria that vary depending on study design. Detailed lists

of criteria and definitions of Good, Fair, or Poor ratings for different study designs appear in Appendix VII of the USPSTF procedure manual .

Data Synthesis

The reviewers used a narrative approach to synthesizing the evidence for all the Key Questions. As indicated in the VA/DoD *Guidelines for Guidelines* document, the first line of evidence was previous systematic reviews. For questions in which a previous review was available, individual studies that met this review's inclusion criteria were used to supplement or update the previous review. The reviewers considered whether subsequent evidence supports the conclusions reported in the previous review. For questions for which no previous review was available, they summarized the overall findings for the outcomes of interest of the studies that addressed a key question.

Assessing the Overall Quality of the Body of Evidence for an Outcome

The overall quality of the body of evidence supporting the findings for the outcomes of interest in this report was assessed using the GRADE system. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system primarily involves consideration of the following factors: overall study quality (or overall risk of bias or study limitations), consistency of evidence, directness of evidence, and precision of evidence. Given time and resources, other factors such as publication bias may also be considered. For more information on the GRADE system go to the GRADE Working Group Web site .

The GRADE system rates the overall quality of the evidence as High, Moderate, Low, and Very Low (see the "Rating Scheme for the Strength of the Evidence" field). For instance, a body of evidence that consists of RCTs automatically starts with a rating of high quality. This rating can be downgraded if some of the RCTs have serious flaws such as lack of blinding of outcome assessors, not reporting concealment of allocation, or high dropout rate. Similarly, the quality can be downgraded or further downgraded if inconsistencies of findings are present or if there is a lack of precision surrounding an outcome's effect size.

Assessing Applicability

When describing the evidence base addressing a Key Question, the reviewers discussed aspects of the included studies, such as characteristics of included patients and treatments being assessed that may make the overall findings of the studies more or less applicable to the population, treatments, or outcomes of interest to this review.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Methods

The current document is an update to the 2007 *Department of Veterans Affairs (VA)/Department of Defense (DoD) Lower Limb Amputation (LLA) Clinical Practice Guideline (CPG)*. The methodology used in developing the 2017 CPG follows the *Guideline for Guidelines*, an internal document of the VA and DoD Evidence-Based Practice Working Group (EBPWG) (see the "Availability of Companion Documents" field). This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions) and other subject matter experts from within the VA and DoD, known as the Work Group, and ultimately, the development and submission of an updated LLA CPG.

The Champions and Work Group for this CPG were charged with developing evidence-based clinical

practice recommendations and writing and publishing a guideline document to be used by providers within the VA/DoD healthcare systems. Specifically, the Champions and Work Group members for this guideline were responsible for identifying the key questions (KQs) of the most clinical relevance, importance, and interest for the rehabilitation of LLA. The Champions and the Work Group also provided direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. The amount of new scientific evidence that had accumulated since the previous version of the CPG was also taken into consideration in the identification of the KQs. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified five clinical leaders, from the DoD, as Champions for the 2017 CPG.

The Lewin Team, including The Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in March 2016, with participation from the contracting officer's representative (COR), leaders from the VA Office of Quality, Safety and Value and the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base a systematic review (SR) about the rehabilitation of LLA. The group also identified a list of clinical specialties and areas of expertise that are important and relevant to rehabilitation of individuals with LLA, from which Work Group members were recruited. The specialties and clinical areas of interest included: physical therapy, occupational therapy, physical medicine and rehabilitation, nursing, pain medicine, psychology, and prosthetics.

The guideline development process for the 2017 CPG update consisted of the following steps:

- Formulating and prioritizing evidence questions (KQs)
- Conducting the SR
- Convening a face-to-face meeting with the CPG Champions and Work Group members
- Drafting and submitting a final CPG to the VA/DoD EBPWG

Appendix A in the original guideline document provides a detailed description of each of these tasks.

Convening the Face-to-face Meeting

In consultation with the (COR), the Champions, and the Work Group, the Lewin Team convened a three and a half day face-to-face meeting of the CPG Champions and Work Group members on September 20-23, 2016. These experts were gathered to develop and draft the clinical recommendations for an update to the 2007 LLA CPG. Lewin presented findings from the evidence review of KQs 1-10 in order to facilitate and inform the process.

Under the direction of the Champions, the Work Group members were charged with interpreting the results of the evidence review, and asked to categorize and carry forward recommendations from the 2007 LLA CPG, modifying the recommendations as necessary. The members also developed new clinical practice recommendations not presented in the 2007 LLA CPG, based on the 2016 evidence review. The subject matter experts were divided into two smaller subgroups at this meeting.

As the Work Group members drafted clinical practice recommendations, they also assigned a grade for each recommendation based on a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) and U.S. Preventive Services Task Force (USPSTF) methodology. Each recommendation was graded by assessing the quality of the overall evidence base, the associated benefits and harms, the variation in values and preferences, and other implications of the

recommendation.

In addition to developing recommendations during the face-to-face meeting, the Work Group members also revised the 2007 LLA CPG algorithms to reflect the new and amended recommendations. They discussed the available evidence as well as changes in clinical practice since 2007, as necessary, to update the algorithms.

Grading Recommendations

This CPG uses the GRADE methodology to assess the quality of the evidence base and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:

- Balance of desirable and undesirable outcomes
- Confidence in the quality of the evidence
- Values and preferences
- Other implications, as appropriate, e.g.:
  - Resource use
  - Equity
  - Acceptability
  - Feasibility
  - Subgroup considerations

The framework in Table A-6 in the original guideline document ("Evidence to Recommendations Framework") was used by the Work Group to guide discussions on each domain.

The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework, which combines the four domains. GRADE methodology does not allow for recommendations to be made based on expert opinion alone. While strong recommendations are usually based on high or moderate confidence in the estimates of effect (quality of the evidence) there may be instances where strong recommendations are warranted even when the quality of evidence is low. In these types of instances where the balance of desirable and undesirable outcomes and values and preferences played large roles in determining the strength of a recommendation, this is explained in the discussion section for the recommendation.

The GRADE of a recommendation is based on the following elements:

- Four decision domains used to determine the strength and direction (described above)
- Relative strength (Strong or Weak)
- Direction (For or Against)

Reconciling 2007 Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current, which typically requires revisions of previous guidelines based on new evidence, or as scheduled, subject to time-based expirations. For example, the U.S. Preventive Services Task Force (USPSTF) has a process for refining or otherwise updating its recommendations pertaining to preventive services. Further, the inclusion criteria for the National Guideline Clearinghouse specify that a guideline must have been developed, reviewed, or revised within the past five years.

The LLA Guideline Work Group focused largely on developing new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition to those new and updated recommendations, the CPG Work Group considered, without complete review of the relevant evidence, the current applicability of other recommendations that were included in the previous 2007 LLA CPG, subject to evolving practice in today's environment.

A set of recommendation categories was adapted from those used by the National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which older recommendations could have been updated. In brief, the

categories took into account whether or not the evidence that related to a recommendation was systematically reviewed, the degree to which the recommendation was modified, and the degree to which a recommendation is relevant in the current patient care environment and inside the scope of the CPG. Additional information regarding these categories and their definitions can be found in Appendix A in the original guideline document. The categories for the recommendations included in the 2017 version of the guideline can be found in "Major Recommendations" field. The categories for the recommendations from the 2007 LLA CPG are noted in Appendix C in the original guideline document.

The CPG Work Group recognized the need to accommodate the transition in evidence rating systems from the 2007 LLA CPG to the current CPG. In order to report the strength of all recommendations using a consistent format (i.e., the GRADE system) the CPG Work Group converted the USPSTF strengths of the recommendation accompanying the carryover recommendations from the 2007 guideline to the GRADE system. As such, the CPG Work Group considered the strength of the evidence cited for each recommendation in the 2007 LLA CPG as well as harms and benefits, values and preferences, and other implications, where possible. The CPG Work Group referred to the available evidence as summarized in the body of the 2007 LLA CPG and did not re-assess the evidence systematically. In some instances, peer-reviewed literature published since the 2007 LLA CPG was considered along with the evidence base used for that CPG. Where such newer literature was considered when converting the strength of the recommendation from the USPSTF to the GRADE system, it is referenced in the discussion that follows the corresponding recommendation, as well as in Appendix B in the original guideline document.

The CPG Work Group recognizes that, while there are practical reasons for incorporating findings from a previous evidence review, previous recommendations, or recent peer-reviewed publications into an updated CPG, doing so does not involve an original, comprehensive SR and, therefore, may introduce bias.

It is important to note that the 2007 LLA CPG based many recommendations on expert opinion alone and were therefore not considered to be evidence-based. While the USPSTF grading system allows for recommendations to be based on expert opinion alone, the GRADE system does not. Therefore, while the 2017 CPG Work Group recognized that many of the 2007 recommendations based on expert opinion alone contained valuable clinical concepts, these 2007 recommendations were not carried forward to this guideline update. However, some of these clinical concepts are discussed in the guideline narrative.

Drafting and Submitting the Final Clinical Practice Guideline

Following the face-to-face meeting, the Champions and Work Group members were given writing assignments to craft discussion sections to support each of the new recommendations and/or to update discussion sections from the 2007 LLA CPG to support the amended "carried forward" recommendations. The Work Group also considered tables, appendices, and other sections from the 2007 LLA CPG for inclusion in the update. During this time, the Champions and Work Group also made additional revisions to the algorithms, as necessary.

Rating Scheme for the Strength of the Recommendations

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

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Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

For use in the 2017 lower limb amputation (LLA) clinical practice guideline (CPG), a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2007 LLA CPG.

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

See Appendix A in the original guideline document for further details on categorization.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After developing the initial draft of the updated clinical practice guideline (CPG), an iterative review process was used to solicit feedback on and make revisions to the CPG. Once they were developed, the first two drafts of the CPG were posted on a wiki website for a period of 14 to 20 business days for internal review and comment by the Work Group. All feedback submitted during each review period was reviewed and discussed by the Work Group and appropriate revisions were made to the CPG.

Draft 3 of the CPG was made available for peer review and comment. This process is described in Peer Review Process section of the original guideline document. After revisions were made based on the feedback received during the peer review and comment period, the Champions presented the CPG to the EBPWG for their approval. Changes were made based on feedback from the Evidence Based Practice Work Group (EBPWG) and the guideline was finalized.

The final 2017 Lower Limb Amputation (LLA) CPG was submitted to the EBPWG in September, 2017.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Table A-4 in the original guideline document indicates the number and type of studies that addressed each of the key questions. The literature review encompassed interventional studies (primarily randomized controlled trials [RCTs]) as well as observational studies, and diagnostic tests studies.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The expected outcome of successful implementation of this guideline is to:

Assess the patient's condition and in collaboration with the patient, determine the most appropriate rehabilitation plan
Optimize each individual's functional independence, health outcomes, and quality of life
Minimize preventable complications and morbidity
Emphasize the use of patient-centered care

Refer to the "Discussion" sections following each recommendation in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Potential Harms

- The potential disadvantages of early mobilization include the risk of skin breakdown of the residual limb, increased residual limb pain, and increased risk of falls.
- Sedation and balance issues from opioids may impede the rehabilitation progress.

Refer to the "Discussion" sections following each recommendation in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Qualifying Statements

Qualifying Statements

- The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.
- This clinical practice guideline (CPG) is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.
- Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.
- These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.
- As with other CPGs, challenges remain with guideline development and the implementation and assessment of the eventual impact the guidelines will have on clinical outcomes. Principal limitations in forming comprehensive CPGs include existing gaps in clinical evidenced-based research that demonstrate sufficient efficacy of interventions. As elaborated in the qualifying statement above, this CPG is not intended to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and patterns evolve. This CPG is based on evidence available through July 2016 and is intended to provide a general guide to best practices. The guideline can assist care providers, but the use of a CPG must always be considered as a recommendation, within the context of a provider's clinical judgment and patient values and preferences, for the care of an individual patient.

Implementation of the Guideline

Description of Implementation Strategy

This clinical practice guideline (CPG) and algorithm are designed to be adapted by individual healthcare providers with consideration of local needs and resources. The algorithm serves as a tool to prompt providers to consider key decision points in the course of an episode of care.

Although this CPG represents the recommended practice on the date of its publication, medical practice is evolving and this evolution requires continuous updating based on published information. New technology and more research will improve patient care in the future. The CPG can assist in identifying priority areas for research and to inform optimal allocation of resources. Future studies examining the results of CPG implementation may lead to the development of new evidence particularly relevant to clinical practice.

Implementation Tools

Clinical Algorithm

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Rehabilitation of Individuals with Lower Limb Amputation Work Group. VA/DoD clinical practice guideline for rehabilitation of individuals with lower limb amputation. Version 2.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 123 p. [133 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Sep

Guideline Developer(s)

Department of Defense - Federal Government Agency [U.S.]

Department of Veterans Affairs - Federal Government Agency [U.S.]

Veterans Health Administration - Federal Government Agency [U.S.]

Source(s) of Funding

United States Government

Guideline Committee

Rehabilitation of Individuals with Lower Limb Amputation Work Group

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Financial Disclosures/Conflicts of Interest

Conflict of Interest

At the start of this guideline development process and at other key points throughout, the project team was required to submit disclosure statements to reveal any areas of potential conflict of interest (COI) in the past 24 months. Verbal affirmations of no COI were used as necessary during meetings throughout the guideline development process. The project team was also subject to random web-based surveillance (e.g., ProPublica).

If a project team member reported a COI (actual or potential), then it was reported to the Office of Evidence Based Practice. It was also discussed with the Lower Limb Amputation (LLA) Clinical Practice Guideline (CPG) Work Group in tandem with their review of the evidence and development of recommendations. The Office of Evidence Based Practice and the LLA CPG Work Group determined whether or not action, such as restricting participation and/or voting on sections related to the conflict or removal from the Work Group, was necessary. If it was deemed necessary, action was taken by the co-chairs and Office of Evidence Based Practice, based on the level and extent of involvement. No conflicts of interest were identified for the LLA CPG Work Group members or Champions. Disclosure forms are on file with the Department of Veterans Affairs Evidence Based Practice Program office and available upon request.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for rehabilitation of lower amputation. Washington (DC): Department of Veterans Affairs, Department of Defense; 2007. 163 p. [71 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Department of Veterans Affairs (VA) Web site .

Availability of Companion Documents

The following are available:

VA/DoD clinical practice guideline for rehabilitation of individuals with lower limb amputation. Version 2.0. Clinician summary. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 28 p. Available from the Department of Veterans Affairs (VA) Web site .

VA/DoD clinical practice guideline for rehabilitation of individuals with lower limb amputation. Version 2.0. Pocket card. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 5 p. Available from the VA Web site .

Guideline for guidelines. Washington (DC): Department of Veterans Affairs; 2013 Apr 10. 26 p. Available from the VA Web site .

Putting clinical practice guidelines to work in VHA. Washington (DC): Department of Veterans Affairs. 64 p. Available from the VA Web site .

Patient Resources

The following is available:

VA/DoD clinical practice guideline for rehabilitation of individuals with lower limb amputation. Version 2.0. Patient guide. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 5 p. Available from the Department of Veterans Affairs (VA) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 29, 2008. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on February 13, 2018. The updated information was verified by the guideline developer on February 26, 2018.

This NEATS assessment was completed by ECRI Institute on January 8, 2018. The information was verified by the guideline developer on February 26, 2018.

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